UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

CHANGE TRANSMITTAL SHEET

DIRECTIVE
REVISION
AMENDMENT
OTHER

Microbial Sampling of Ready-to-Eat (RTE) Products	10,240.2 Revision 1 Amend. 1	1/24/01

I. Why is FSIS issuing this change transmittal?

This change transmittal provides corrected pages to FSIS Directive 10,240.2, revision 1.

II. What are the changes?

On page 2 of the directive, FSIS has clarified the meaning of the term ready-to-eat (RTE). FSIS realized that under several of the categories, an establishment can produce both RTE and Not-RTE products. For example, an establishment may determine that certain not heat treated, shelf stable products, such as country ham, dry cured ham, country style pork shoulder, and similar pork products, may be either RTE or Not-RTE based on how the establishment produces and labels these products. FSIS has changed this page. Also, FSIS has made the necessary changes to the chart (Attachment 2) to reflect this change.

On page 4 under VII., B., FSIS added a note. FSIS has determined that it is not necessary for inspection program personnel to routinely collect lard, margarine or lard margarine, mixtures of rendered animal fats, popped pork skins, pork rinds, or dried soup base samples. Inspection program personnel should only collect these products if specifically instructed to do so in Block 18 on FSIS Form 10,210-3.

III. Cancellation

This transmittal is cancelled when contents have been incorporated into FSIS Directive 10,240.2, Revision 1.

/s/ Philip S. Derfler

Deputy Administrator
Office of Policy, Program Development
And Evaluation

FILING INSTRUCTION

Remove Old Pages	Insert New Pages
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UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
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FSIS DIRECTIVE

10,240.2
Revision 1
Amend. 1

MICROBIAL SAMPLING OF READY-TO-EAT (RTE) PRODUCTS

I. PURPOSE

This directive provides inspection program personnel with instructions for sampling ready-to-eat (RTE) meat and poultry products produced in official establishments. Additionally, it outlines the regulatory actions FSIS will initiate when a sample of such product tests positive for a microbial hazard, such as *Salmonella, Listeria monocytogenes, E. coli* O157:H7*, and* staphylococcal enterotoxin. **NOTE: DO NOT IMPLEMENT THE INSTRUCTIONS IN THIS DIRECTIVE UNTIL DECEMBER 1, 2000.**

II. CANCELLATION

FSIS Directive 10,240.2, Amendment 1, dated 12-18-98
FSIS Directive 10,240.1, Revision 1, dated 8-30-90

III. REASON FOR RE-ISSUANCE

A. to clarify the role of FSIS microbiological sampling of RTE product under HACCP.

B. to provide the procedures inspection program personnel follow when an establishment that produces RTE product incorporates pathogen testing into its Sanitation SOP's and HACCP plans.

IV. REFERENCES

Part 417 of the Federal meat and poultry products inspection regulations
FSIS Directive 10,210.1, Amend. 2, dated 10/16/00
FSIS Directive 5000.1, dated 11/21/97
FSIS Directive 5400.5, dated 11/21/97
FSIS Directive 8080.1, Revision 3, dated 1/19/00

V. TERMINOLOGY

What terms will we use in this directive?

Ready-to-Eat (RTE) Product – Product that is intended to be consumed without any further safety preparation steps. FSIS will sample and test RTE products produced under the following processing categories:

A. not heat treated—shelf stable (9 CFR 417.2(b)(v), ISP activity number 03E)

B. heat treated—shelf stable (9 CFR 417.2(b)(vi), ISP activity number 03F)

C. fully cooked—not shelf stable (9 CFR 417.2(b)(vii), ISP activity number 03G)

D. product with secondary inhibitors—not shelf stable, (9 CFR 417.2(b)(ix), ISP number 03I).

NOTE: FSIS is aware that establishments may produce RTE and Not-RTE products under A, B, and D. Attachment 2 provides further guidance regarding how establishments and inspection program personnel may determine whether a product is RTE or Not-RTE. When collecting samples from these categories, inspection program personnel should only collect RTE product. Also, for products that can be RTE or Not-RTE, inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance for a Not-RTE product as described in Attachment 2.

Sample – A collection of product that represents a larger group (the sampled lot) that has passed the establishment's pre-shipment HACCP review. The sample should be in its consumer-ready package state whenever possible. When this is not possible (e.g., the shipping container is too large to mail), inspection program personnel may permit the establishment to short-weight or slack-fill a container. In such cases, the sample must be produced in the same way as the rest of the product it represents; the only difference would be the size of the package. Minimum sample sizes for analysis are defined in FSIS Directive 10,210.1 or are provided in block 18 of the sample request form, FSIS Form 10,230-3.

Sampled Lot - This is the amount of product represented by the sample. The establishment defines the sampled lot. As a guide, FSIS considers all product produced under a single HACCP plan between performance of complete cleaning and sanitizing procedures (clean-up to clean-up, including start to finish under extended clean-ups) to be an appropriate definition of a sampled lot. In situations where recall, retention, or seizure is necessary, FSIS may determine that more product or less product than that produced from clean-up to clean-up under the HACCP plan is represented by the sample. In making this determination, FSIS will consider such factors as the establishment's coding of product; the pathogen of concern; the processing and packaging; the equipment; the establishment's testing under its HACCP plan; the establishment's HACCP plan monitoring and verification activities performed in accordance with 417.2 and 417.4; Sanitation SOP records as required in 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.

VI. POLICY

A. FSIS verifies the adequacy of an establishment's HACCP system by determining whether HACCP plans meet the requirements of 9 CFR Part 417 and all other applicable regulations, and whether the system is being operated as planned. Verification activities include, but are not limited to, collecting and testing RTE products for microbial hazards. FSIS Directive 10,210.1 Amendment 2, Unified Sampling Form, lists the products and pathogens and toxins for which FSIS may test samples. For example, FSIS may analyze a not heat treated, shelf stable ready-to-eat meat and poultry product for *Salmonella* AND *Listeria monocytogenes*, and if the product is a dry or semi-dry fermented sausages, the product will also be analyzed for *E. coli* O157:H7 and staphylococcal enterotoxin.

B. If a sample tests positive for a microbial hazard, FSIS expects establishments to: (1) take corrective and preventive measures and conduct reassessments in accordance with 9 CFR Part 417 and (2) recall from commerce any product represented by that sample. Inspection program personnel will follow the instructions in FSIS Directive 5000.1 to verify that the establishment complied with 9 CFR part 417. The Recall Management Division (RMD) will coordinate any recall activity as outlined in FSIS Directive 8080.1, Revision 3. Note: The cause of a positive finding in RTE product varies from case to case, based on the pathogen or toxin found, and the type of processing involved. Before making its determination, FSIS will consider the entire situation. This includes whether some or all products produced under the same or a substantially similar HACCP plan have been affected, what pathogens or toxins are involved, whether there have been any other incidents of contamination in the establishment associated with the pathogen or toxin, and whether there have been persistent and recurring noncompliances in the establishment.

VII. SAMPLING

What are the sampling procedures?

A. When a sample is scheduled to be taken at an establishment, the Inspector-in-Charge (IIC) receives FSIS Form 10,210-3, “Requested Sample Programs” from the Office of Public Health and Science (OPHS). When the form is sent, certain blocks will be pre-printed with information specific to the sample to be collected. Using the project code in **Block 14** of the form, follow the corresponding instructions found in FSIS Directive 10,210.1, Amend. 2 for collecting and shipping samples. **NOTE**: OPHS has changed the project code numbers in **Block 14** to correspond to the 03 HACCP processing categories (see definition of RTE products).

B. Unless the establishment meets the criteria in section VIII, randomly collect a sample from a RTE product produced under the project number listed in **Block 14** of FSIS Form 10,210-3. The IIC will oversee the sample collection to ensure that different products are sampled each time sample request forms are received. **NOTE**: FSIS has determined that it is not necessary for inspection program personnel to routinely collect lard, margarine or lard margarine, mixtures of rendered animal fats, popped pork skins, pork rinds, or dried soup base samples. If FSIS Form 10,210-3 is received and the only RTE product(s) produced by the establishment under the designated process code is one of these products, inspection program personnel should check code 53 in block 33, make a note as to which of these products are produced, and return the form to the laboratory. If FSIS deems it necessary to sample these products in the future, an FSIS Form 10,210-3 will be sent with special notation in Block 18 regarding the sampling of one or more of these products.

C. Provide the establishment management enough time to hold all product the establishment determines to be represented by the sample, i.e., the sampled lot. Coordinate with the establishment management to determine at what time to provide the notification. In some cases, inspection program personnel may need to inform the establishment a number of hours or days in advance, such as for establishments operating under an extended clean-up or because of the production process involved (e.g., the production of dry and semi-dry fermented sausages.)

D. If possible, **only** collect and mail the samples from the establishment's current day's production that has passed the establishment's pre-shipment record review (see § 417.5(c)). If not possible, such as in establishments where production is held off-site prior to completion of the pre-shipment record review, or the pre-shipment review is performed at a later date, collect samples of the current day's production, refrigerate or freeze them, keep them in a secure location, and postpone mailing the samples until the pre-shipment record review is complete, and the product is eligible for shipment. After the establishment completes the pre-shipment review, inspection program personnel should prepare the samples to be sent to the laboratory on the next available Federal Express pickup day.

E. Complete all requested information in Part II of the FSIS Form 10,210-3, as described in FSIS Directive 10,210.1, Amend. 2. The FSIS laboratories are to discard any samples with incomplete forms.

F. Record the sample collection as a performed, unscheduled 05B02 on FSIS Form 5400-5.

VIII. Verification of Establishment Testing

When should samples not be collected?

Unless otherwise instructed via the FSIS Form 10,210-3, inspection program personnel should not collect samples at an establishment that:

A. At a minimum, tests one RTE product per HACCP plan for the pathogens and toxins listed in **Block 13** of FSIS Form 10,210-3 once a month; or

6. **Question:** If an establishment or its customers conduct their own testing on RTE products and find a pathogen or toxin, is this a noncompliance for which inspection program personnel would complete a Noncompliance Record (NR)?

   Answer: No. In and of itself, an establishment or its customers' finding of a pathogen or toxin in RTE product is not a noncompliance. Establishments are required to ensure that their HACCP plan is producing product in accordance with Part 417 of the regulations and that adulterated product is not produced and shipped. FSIS will make a determination based on the information provided by the establishment or its customers as to whether adulterated product entered commerce and is subject to retention, detention, voluntary recall, or seizure.

7. **Question**: Can establishments use product that tested positive for a pathogen as "re-work?" Are there special restrictions?

   Answer: The regulations do not prohibit the use of product that tested positive for a pathogen as "re-work." An establishment is expected to address the use of such product in its HACCP plan. The plan must address any hazards presented by the practice such as the potential hazard of increased tolerance of bacteria that survived a "kill" step. If the practice of re-working such product is done all the time, then critical limits and critical control points need to account for any potential added hazards. If the practice is done occasionally, the plan may only need to address the procedures, critical limits, and critical control points to be met when lots containing re-work are processed. When product that tested positive is identified after it has left an establishment, it may be moved under control to an establishment where it can be further processed.

FOLLOW-UP SAMPLING

8. **Question:** During follow-up sampling, must the samples be collected on consecutive production days?

   Answer: Block 4 of FSIS Form 10,210-3 will show the timeframe for collecting the follow-up samples. Samples do not have to be collected on consecutive production days. The purpose of the follow-up sampling is to verify the effectiveness of establishment's corrective and preventive measures.

TYPE	CLASS	PROCESSING CATEGORY ISP CODE	REG REQUIRED SAFETY LABELING	WHAT THE HAZARD ANALYSIS/HACCP PLAN MAY ADDRESS
A product containing a meat/poultry product (in whole or in part) which **has not** received an adequate lethality treatment for pathogens (i.e. raw or partially cooked product).	NRTE	• Raw Product Ground – ISP 03B • Raw Product Not Ground – ISP 03C • Not Heat Treated Shelf Stable – ISP 03E • Heat Treated –shelf stable – ISP 03F • Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H • Products with secondary inhibitors Not Shelf Stable – ISP 03I •	Product must be labeled with statements such as keep refrigerated , keep frozen, or refrigerate leftovers. Use of Safe Handling Instruction (SHI) labeling required.	• Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). If it is not obvious that the product is raw and needs to be cooked: • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., "Cook and Serve") but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as "needs to be fully cooked," "see cooking instructions," or "cook before eating." • Validation that: a. Cooking and preparation instructions on the product are sufficient to destroy pathogens. b. Instructions are realistic for the intended consumer.
A product containing a meat/poultry component that **has** received a lethality treatment for pathogens in combination with non-meat/poultry components that **need** to receive a lethality treatment by the intended user. This includes meals, dinners, frozen entrees.	NRTE	• Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H	Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended.	• Validation that: a. The meat/poultry component received an adequate lethality treatment for pathogens. b. Cooking and preparation instructions on the product are sufficient to destroy pathogens. c. Instructions are realistic for the intended consumer. • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., "Cook and Serve") but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as "needs to be fully cooked," "see cooking instructions," or "cook before eating." • If necessary, hazard analysis should address whether instructions on the label are needed related to cross-contamination (e.g., avoid contact of contents) and prevention of pathogenic growth (e.g., promptly refrigerate leftovers). NOTE: inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance above.
A product containing a meat/poultry component that **has** received a lethality treatment for pathogens that may or may not be in combination with a non-meat/ poultry component that does **not** need to receive a lethality treatment by the intended user.	RTE	• Not Heat Treated Shelf Stable – ISP 03E • Heat Treated Shelf Stable – ISP 03F • Fully Cooked Not Shelf Stable – ISP 03G • Products with secondary inhibitors Not Shelf Stable – ISP 03I	If the product is not shelf stable labeling such as keep refrigerated or frozen is required.	• See part 417 of the meat and poultry regulations.